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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/724,419	11/28/2000	Peter Palese	6923-102	9897

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PENNIE AND EDMONDS
1155 AVENUE OF THE AMERICAS
NEW YORK, NY 100362711

EXAMINER	
LANKFORD JR, LEON B	

ART UNIT	PAPER NUMBER
1651	21

DATE MAILED: 08/26/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/724,419	PALESE ET AL.	
	Examiner	Art Unit	
	L Blaine Lankford	1651	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *11 June 2003* .

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *41-57 and 71-78* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *41-57 71-78* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Applicant's arguments filed 6-11-03 have been fully considered but they are not persuasive. The claims remain rejected for the reasons of record. Applicant's arguments have been considered however a showing to overcome a prima facie case of obviousness must be clear and convincing(In re Lohr et al. 137 USPQ 548) as well as commensurate in scope with the claimed subject matter (In re Lindner 173 USPQ 356; In re Hyson, 172 USPQ 399 and In re Boesch et al., 205 USPQ 215 (CCPA 1980). Applicant claims unexpectedly better results from utilizing the claimed invention, however the clear superiority alleged has not been objectively demonstrated or pointed out. Were applicant to show how such results were unexpected, claims commensurate in scope with that showing would be allowable. The results applicant alleges are unexpected may be commensurate in scope with some of the claimed subject matter but the arguments are not so pointed. It would appear a chicken egg of a particular age infected by specific viruses may reach an unexpected level of growth but the arguments focus on the broader age range which the examiner believes to still be obvious over the prior art of record.

Applicant argues that the accepted means for growing influenza virus is a 10-12 day old chick egg, however it is clear that the prior art suggests a range for growing RNA viruses in chick eggs as young as 8 days old. The art teaches that such a substrate is a useful vehicle for growing a variety of viruses therefore the claimed invention would have been obvious at the time the invention was made.

The viral strains used by applicant are known viral variants grown in substrates known to be receptive to viral infection and conducive for replication. Thus, it would have been obvious at the time the invention was made to infect less than 10 day old chick eggs with the claim designated viruses yielding an infected egg.

Claims 41-57 & 71-78 are rejected under 35 U.S.C. 103(a) as being unpatentable over Mitsubishi (4659569) and Sasaki et al(JP 59-29831).

Applicant claims an egg infected by a mutated influenza virus.

Mitsubishi and Sasaki teach that embryonated eggs under 10 days old are susceptible to virus infection and replication particularly to influenza viruses. The references clearly disclose eggs infected with viruses, particularly influenza. The references do not teach the specific viral strains which are now claimed however composition of young embryonated eggs infected with the claim designated strains would have been obvious to one of ordinary skill in the art at the time the invention was made because it is notoriously old and well known in the art to propagate viruses in such eggs and one would have been motivated to make the composition because one would reasonably expect the infected egg to yield replicated virus.

As the references clearly indicate that the various proportions and amounts of the ingredients used in the claimed composition are result effective variables, they would be routinely optimized by one of ordinary skill in the art in practicing the invention disclosed by those references.

Applicant would appear to allege criticality with regard to the strain of virus in the composition. However, there is not clear and convincing evidence of criticality now of record. The slight difference in results described in the specification would appear to be no more than a difference of degree rather than a difference in kind. This type of evidence is insufficient to overcome a prima facie case of obviousness.

Accordingly, the claimed invention was prima facie obvious to one of ordinary skill in the art at the time the invention was made especially in the absence of evidence to the contrary.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to L Blaine Lankford whose telephone number is 308-2455. The examiner can normally be reached on Mon-Thu 7:30-6.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mike Wityshyn can be reached on 308-4743. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 308-0196.

L Blaine Lankford
Primary Examiner
Art Unit 1651

LBL
August 25, 2003